

REMARKS

**Reconsideration And Allowance
Are Respectfully Requested.**

Claims 17-20 are currently pending. No claims have been amended. Claims 1-16, 20 and 21 were previously canceled. No claims have been canceled by way of the present amendment. No new claims have been added. No new matter has been added. Reconsideration is respectfully requested.

The outstanding Office Action presents a new ground of rejection relating to pending claims 17-20. In particular, claims 17-20 now stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,159,196 to Ruiz ("Ruiz") in view of an article entitled "Sclerosant Treatment of Varicose Veins and Deep Vein Thrombosis" by R.A. Williams et al. ("Williams").

The Office Action argues that Ruiz discloses the claimed invention with the exception of the injection of sclerosant into the vein at the treatment site so as to cause irreversible damage to the endothelium at the treatment site by reducing the blood volume in the vein at the treatment site. In addressing this deficiency, the Examiner cites Williams. The Examiner argues that Williams teaches the step of injecting sclerosant into the vein at the treatment site and that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Ruiz by injecting sclerosant into the vein at the treatment site as taught by Williams. In particular, the Examiner states that the use of sclerosant as taught by Williams would be "in order

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to produce an irreversible endothelial damage in the area under the treatment and is a well known agent for use in revascularization". It is Applicant's opinion the basis for the combination proposed in the outstanding Office Action is incorrect and the application of a sclerosant as suggested in the Office Action would destroy the reference of Ruiz. It is not obvious to inject a sclerosant in conjunction with the disruption or irritation of the surface of a vein wall as claimed in accordance with the present invention.

In establishing a *prima facie* obviousness-type rejection, the Examiner must find a rationale or rational underpinning to modify or combine the references. Ruiz specifically employs the elongated vascular probe to promote revascularization. Revascularization and angiogenesis is promotion of blood vessel growth and enhancement of blood vessel patency. This is in contrast to the purpose of the claimed invention and Wilson's use of sclerosant, which are aimed at permanently destroying and occluding a vein. In particular, and with reference to Column 4, lines 35-43, Ruiz states, "[t]he elongated vascular probe may be configured as an angiogenic vascular stimulator to provide a net beneficial angiogenic response that promotes revascularization by effecting a controlled injury to the wall of a blood vessel such as a vein. The perforating members of the vascular probe may also extend through the blood vessel such as a coronary vein towards adjacent muscle such as the myocardium". As such, and considering Ruiz's intention to promote revascularization, which the Office Action acknowledges as an important component of Ruiz's invention, the application of a sclerosant to the injured wall would be contrary to Ruiz's intention for revascularization. In particular, the application of a sclerosant would result in the destruction of the vessel and the surrounding vessels, not the revascularization of the area injured as

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contemplated by Ruiz. In addition, Ruiz states that the vascular probe may extend beyond the

vessel wall to promote injection of therapy and subsequent revascularization. Injection of sclerosant outside of the vein wall as proposed in the outstanding rejection would be detrimental and likely cause significant complications such as ulceration and scarring.

As discussed in "Complications of Sclerotherapy", Munavalli et al., and "Extensive Tissue Necrosis Following High-Concentration Sclerotherapy for Varicose Veins", Bergan et al., those skilled in the art clearly understand the application of sclerosants is utilized to provoke a marked damage of the endothelium of the vessels and incite eventual transmural (that is, affecting all layers) wall damage with subsequent transformation of the veins into a fibrous cord, thus resulting in the complete destruction of the vein. This is entirely contrary to the goals of Ruiz.

Accordingly, and considering the requirement that a *prima facie* case of obviousness is only established when the Examiner establishes a suggestion or motivation for modification and a potential for success in the modification of the primary reference so as to read upon the pending claims, it is readily apparent that the utilization of a sclerosant in conjunction with the teachings of Ruiz is entirely contrary to Ruiz and would not result in a successful methodology for use in promoting revascularization as proposed by Ruiz.

In addition, the claims require the creation of a spasm of the vein at the treatment site. Such a step is neither disclosed nor suggested by Ruiz (or Williams). With this in mind, the Office Action states, "[t]he intended use of disrupting or irritating the surface of a vein wall must result in additional steps to be performed between the claimed invention and the prior art in order to patently distinguish the claimed invention from the prior art. Since the prior art is

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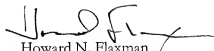
capable of performing the intended use, then it meets the claim; see MPEP 2106". As best

understood by Applicant, this statement overlooks the fact Applicant is not claiming an apparatus, but is claiming a method. As such, there is no "intended use" to be found in the claims but actual use specifically relating to the claimed method and explicitly required by the claimed method. The Office Action may, there, not simply dismiss claim limitations as relating to "intended use".

With the foregoing in mind, it is Applicant's opinion the outstanding rejection is improper and Applicant accordingly respectfully requests the rejection be withdrawn. Ultimately, the claimed combination of injecting a sclerosant with the application of mechanical damage to the surface of the vein wall is not obvious as it is neither taught nor disclosed in by the cited references.

It is believed that this case is in condition for allowance and reconsideration thereof and early issuance is respectfully requested. If it is felt that an interview would expedite prosecution of this application, please do not hesitate to contact Applicant's representative at the below number.

Respectfully submitted,


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Our Docket No. TAL-001